

§ 80.22

size of containers, location, etc.)
Certification requested for use in _____

(State proposed uses)

Required fee, \$—— (drawn to the order of
Food and Drug Administration).

The accompanying sample was taken after
the batch was mixed in accordance with 21
CFR 80.22 and is accurately representative
thereof.

(Signed) _____

By _____

(Title)

[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar.
23, 1979; 44 FR 22053, Apr. 13, 1979, as amended
at 54 FR 24890, June 12, 1989; 61 FR 14479, Apr.
2, 1996]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive
which is to accompany a request for
certification shall:

(a) Be taken only after such batch
has been so thoroughly mixed as to be
of uniform composition throughout.

(b) Held under the control of the per-
son requesting certification until cer-
tified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch num-
ber.

(3) The quantity of such batch.

(4) The name and post-office address
of the person requesting certification
of such batch.

(5) Be accompanied by any label or
labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines,
after such investigations as he consid-
ers to be necessary, that:

(1) A request submitted in accordance
with § 80.21 appears to contain no un-
true statement of a material fact;

(2) Such color additive conforms to
the specifications and any other condi-
tions set forth therefor in parts 81 and
82 of this chapter.

(3) The batch covered by such request
otherwise appears to comply with the
regulations in this chapter, the Com-
missioner shall issue to the person who
submitted such request a certificate
showing the lot number assigned to
such batch and that such batch, subject

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to the terms, conditions, and restric-
tions prescribed by part 74, 81, and 82 of
this chapter, is a certified batch.

(b) If the Commissioner determines,
after such investigation as he considers
to be necessary, that a request submit-
ted in accordance with § 80.21, or the
batch of color additive covered by such
request, does not comply with the re-
quirements prescribed by paragraph (a)
of this section for the issuance of a cer-
tificate, the Commissioner shall refuse
to certify such batch and shall give no-
tice thereof to the person who submit-
ted such request, stating his reasons
for refusal. Any person who contests
such refusal shall have an opportunity
for a regulatory hearing before the
Food and Drug Administration pursu-
ant to part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained
through fraud or misrepresentation of
a material fact, such certificate shall
not be effective, and a color additive
from the batch on which such certi-
ficate was issued shall be considered to
be from a batch that has not been cer-
tified in accordance with the regula-
tions in this part. Whenever, the Com-
missioner learns that any certificate
has been obtained through fraud or ma-
terial misrepresentation, he shall no-
tify the holder of the certificate that it
is of no effect.

(b) If between the time a sample of
color additive accompanying a request
for certification is taken and the time
a certificate covering the batch of such
color additive is received by the person
to whom it is issued, any such color ad-
ditive becomes changed in composi-
tion, such certificates shall not be ef-
fective with respect to such changed
color additive and such changed color
additive shall be considered to be from
a batch that has not been certified in
accordance with the regulations in this
part.

(c) If at any time after a certificate
is received by the person to whom it is
issued any color additive from the
batch covered by such certificate be-
comes changed in composition, such
certificate shall expire with respect to
such changed color additive. After such
expiration, such color additive shall be
considered to be from a batch that has